



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Samsung Medison Co., Ltd.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services
1394 25th Street, NW
BUFFALO MN 55313

November 26, 2014

Re: K143089
Trade/Device Name: WS80A Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: October 27, 2014
Received: October 28, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the WS80A Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

SC1-6	C2-6	E3-12A
VR5-9	L3-12A	L5-13
V4-8	V5-9	CA1-7A
CA2-8A	CF4-9	LA3-16A
PE2-4	CV1-8A	LV3-14A

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert A. Ochs". The signature is written in a cursive style. In the background, there is a large, faint, light-gray watermark of the FDA logo.

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K143089

Device Name

WS80A Diagnostic Ultrasound System

Indications for Use (Describe)

The WS80A Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

The clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric and Peripheral vessel.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: WS80A Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (<i>See Note 3</i>)	P	P	P		P	Note 1	Notes 2, 4, 5, 6, 7, 8, 9, 11
	Abdominal (<i>See Note 10</i>)	P	P	P	P	P	Note 1	Notes 2, 7, 8, 9, 11, 12
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 8, 9, 11
	Small Organ (<i>See Note 5</i>)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11, 12
	Neonatal Cephalic	P	P	P	P	P	Note 1	Notes 7, 8, 9, 11
	Adult Cephalic	P	P	P	P	P	Note 1	Notes 7
	Trans-rectal	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 11, 12
	Trans-vaginal	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 11, 12
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Intra-luminal							
	Other (spec.) (<i>See Note 13</i>)	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 12
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1	Notes 4, 7
	Cardiac Pediatric	P	P	P	P	P	Note 1	Notes 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K133329; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: SC1-6 for use with WS80A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (<i>See Note 3</i>)	P	P	P		P	Note 1	Notes 2, 4, 7, 8, 9, 11
	Abdominal (<i>See Note 10</i>)	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 11
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (<i>See Note 13</i>)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K133329; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, , B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: C2-6 for use with WS80A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (<i>See Note 3</i>)	P	P	P		P	Note 1	Notes 2, 4, 7, 8, 9, 11
	Abdominal (<i>See Note 10</i>)	P	P	P		P	Note 1	Notes 2, 7, 8, 11
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (<i>See Note 13</i>)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K133329; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: E3-12A for use with WS80A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (<i>See Note 3</i>)	P	P	P		P	Note 1	Notes 7, 8, 9
	Abdominal (<i>See Note 10</i>)	P	P	P		P	Note 1	Notes 7, 8, 9, 12
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Notes 7, 8, 9, 12
	Trans-vaginal	P	P	P		P	Note 1	Notes 7, 8, 9, 12
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (<i>See Note 13</i>)	P	P	P		P	Note 1	Notes 7, 8, 9, 12
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K133329; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, , B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: VR5-9 for use with WS80A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (<i>See Note 3</i>)	P	P	P		P	Note 1	Note 2, 7, 8, 9
	Abdominal (<i>See Note 10</i>)	P	P	P		P	Note 1	Note 2, 7, 8, 9, 12
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 8, 9, 12
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8, 9, 12
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (<i>See Note 13</i>)	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 12
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K133329; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: L3-12A for use with WS80A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (<i>See Note 3</i>)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Abdominal (<i>See Note 10</i>)							
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11, 12
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Intra-luminal							
	Other (spec.) (<i>See Note 13</i>)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K133329; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: L5-13 for use with WS80A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (<i>See Note 3</i>)							
	Abdominal (<i>See Note 10</i>)							
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11, 12
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Intra-luminal							
	Other (spec.) (<i>See Note 13</i>)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K133329; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: V4-8 for use with WS80A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (<i>See Note 3</i>)	P	P	P		P	Note 1	Note 2, 4, 7, 8, 9, 11
	Abdominal (<i>See Note 10</i>)	P	P	P		P	Note 1	Note 2, 7, 8, 11
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (<i>See Note 13</i>)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K133329; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: V5-9 for use with WS80A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (<i>See Note 3</i>)	P	P	P		P	Note 1	Note 2, 7, 8, 9
	Abdominal (<i>See Note 10</i>)	P	P	P		P	Note 1	Note 2, 7, 8, 9
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 8, 9
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8, 9
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (<i>See Note 13</i>)	P	P	P		P	Note 1	Notes 2, 7, 8
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K133329; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CA1-7A for use with WS80A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (<i>See Note 3</i>)	P	P	P		P	Note 1	Notes 2, 4, 7, 8, 9, 11
	Abdominal (<i>See Note 10</i>)	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 11
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (<i>See Note 13</i>)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K141620; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, , B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CA2-8A for use with WS80A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (<i>See Note 3</i>)	P	P	P		P	Note 1	Notes 2, 4, 7, 8, 9, 11
	Abdominal (<i>See Note 10</i>)	P	P	P		P	Note 1	Notes 2, 4, 7, 8, 9, 11
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (<i>See Note 13</i>)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K132861; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, , B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CF4-9 for use with WS80A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (<i>See Note 3</i>)							
	Abdominal (<i>See Note 10</i>)	P	P	P		P	Note 1	Notes 8, 9, 11
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 8, 9, 11
	Small Organ (<i>See Note 5</i>)							
	Neonatal Cephalic	P	P	P		P	Note 1	Notes 8, 9, 11
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (<i>See Note 13</i>)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Notes 8, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K141620; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: LA3-16A for use with WS80A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (<i>See Note 3</i>)							
	Abdominal (<i>See Note 10</i>)							
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11, 12
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Intra-luminal							
	Other (<i>See Note 13</i>)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K132861; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: PE2-4 for use with WS80A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (<i>See Note 3</i>)							
	Abdominal (<i>See Note 10</i>)	P	P	P	P	P	Note 1	Note 7
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)							
	Neonatal Cephalic	P	P	P	P	P	Note 1	Note 7
	Adult Cephalic	P	P	P	P	P	Note 1	Note 7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (<i>See Note 13</i>)							
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1	Note 4, 7
	Cardiac Pediatric	P	P	P	P	P	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K141620; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CV1-8A for use with WS80A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (<i>See Note 3</i>)	N	N	N		N	Note 1	Note 2, 4, 7, 8, 9, 11
	Abdominal (<i>See Note 10</i>)	N	N	N		N	Note 1	Note 2, 7, 8, 11
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (<i>See Note 13</i>)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: LV3-14A for use with WS80A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (<i>See Note 3</i>)							
	Abdominal (<i>See Note 10</i>)							
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Intra-luminal							
	Other (<i>See Note 13</i>)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K141620; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1. Submitter's Information: 21 CFR 807.92(a)(1)

SAMSUNG MEDISON CO., LTD.
42, Teheran-ro 108-gil, Gangnam-gu,
Seoul, Korea

Contact Person:

Kyeong-Mi, Park
Regulatory Affairs Manager

Telephone: 82.2.2194.1373
Facsimile: 82.2.556.3974

Data Prepared: September 24, 2014

2. Name of the device:Common/Usual Name:

Diagnostic Ultrasound System and Accessories

Proprietary Name:

WS80A Diagnostic Ultrasound System

<u>Classification Names:</u>	<u>FR Number</u>	<u>Product Code</u>
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasound Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX

3. Identification of the predicate or legally marketed device:

- UGEO WS80A Diagnostic Ultrasound System (K133329)
- RS80A Diagnostic Ultrasound System (K141620)
- UGEO H60 Diagnostic Ultrasound System (K132861)
- Voluson E8 Diagnostic Ultrasound System (K122327)
- ACUSON S2000 Diagnostic Ultrasound System (K130739)

4. Device Description:

The WS80A is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as B mode, M mode, Color Doppler imaging, Power Doppler imaging (including Directional Power Doppler mode; S-Flow), PW Spectral Doppler mode, CW Spectral Doppler mode, Harmonic imaging, Tissue Doppler imaging, Tissue Doppler Wave, 3D imaging mode (real time 4D imaging mode), Elastoscans Mode or as a combination of these modes. The WS80A also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information that is used to make a diagnosis by competent health care professionals. The WS80A has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

5. Intended Uses:

The WS80A Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

The clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric and Peripheral vessel.

6. Technological Characteristics:

The WS80A is substantially equivalent with respect to safety, effectiveness, and functionality to the UGEO WS80A Diagnostic Ultrasound System (K133329), RS80A Diagnostic Ultrasound System (K141620) and UGEO H60 Diagnostic Ultrasound System (K132861).

It is substantially equivalent with respect to safety, effectiveness, and functionality to the [Synco Auto OB Measurements⁴⁾] of Siemens's ACUSON S2000 (K130739) in regards to the device with [5D CNS]. It is substantially equivalent with respect to safety, effectiveness, and functionality to the [SonoAVC follicle⁵⁾ and SonoVCAD heart⁶⁾] of GE's Voluson E8 (K122327) in regards to the device with [5D Follicle and 5D Heart].

All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All system allow for specialized measurements of structures and flow, and calculations.

These are described in detail in the technological characteristics comparison table as below.

<Change list>

	WS80A (V2.00)	Comment																
Model Name	<ul style="list-style-type: none">Change of model name in the V2.00	The model name in the V1.00 is UGEO WS80A.																
Clinical application	<ul style="list-style-type: none">Addition of clinical applications : Pediatric, Neonatal Cephalic, Adult Cephalic, Cardiac Adult, Cardiac Pediatric																	
Operation of modes	<ul style="list-style-type: none">Addition of Continuous Wave (CW) Spectral Doppler																	
Applied transducers	<ul style="list-style-type: none">Addition of 7 transducers : CA1-7A, CA2-8A, CF4-9, LA3-16A, PE2-4, CV1-8A and LV3-14A.	<table><tr><th>Transducers</th><th>The previously cleared transducers</th></tr><tr><td>CA1-7A</td><td>K141620</td></tr><tr><td>CA2-8A</td><td>K132861 (CF2-8)</td></tr><tr><td>CF4-9</td><td>K141620</td></tr><tr><td>LA3-16A</td><td>K132861 (LF5-13)</td></tr><tr><td>PE2-4</td><td>K141620</td></tr><tr><td>LV3-14A</td><td>K141620</td></tr><tr><td>CV1-8A</td><td>None</td></tr></table>	Transducers	The previously cleared transducers	CA1-7A	K141620	CA2-8A	K132861 (CF2-8)	CF4-9	K141620	LA3-16A	K132861 (LF5-13)	PE2-4	K141620	LV3-14A	K141620	CV1-8A	None
Transducers	The previously cleared transducers																	
CA1-7A	K141620																	
CA2-8A	K132861 (CF2-8)																	
CF4-9	K141620																	
LA3-16A	K132861 (LF5-13)																	
PE2-4	K141620																	
LV3-14A	K141620																	
CV1-8A	None																	
SW Features	<ul style="list-style-type: none">Addition of S/W Features : (new) 5D CNS, 5D Follicle and 5D Heart (previously cleared) RMSChange of S/W feature’s name : SCI→MultiVision, SDMR→ClearVision, FRV→Realistic Vue	<p>Description of S/W Features</p> <ul style="list-style-type: none">5D CNS: This feature assists with diagnosis by taking measurements relating to fetal brain.5D Follicle: This feature assists with diagnosis by estimating the size and volume of a follicle in the ovary5D Heart: This feature assists with diagnosis of fetal heart conditions by using the STIC data of the fetus.RMS: This feature is the collection of error data in the ultrasound imaging system, utilization logging, and the control of remote device. The collected data is transmitted to the RMS server over a network for customer service.																
HW Features	<ul style="list-style-type: none">Change of Monitor size and Physical DimensionsAddition of CW Probe Port																	

<Technological Characteristics Comparison Table>

Feature / Characteristics	The subject device	The predicate devices				
	WS80A	UGEO WS80A (K133329)	RS80A (K141620)	UGEO H60 (K132861)	Voluson E8 (K122327)	ACUSON S2000 (K130739)
Indication for Use						
- Fetal/Obstetrics	√	√	√	√	√	√
- Abdominal	√	√	√	√	√	√
- Gynecology	√	√	√	√	√	
- Pediatric	√		√	√	√	√
- Small Organ	√	√	√	√	√	√
- Neonatal Cephalic	√		√	√	√	√
- Adult Cephalic	√		√	√	√	√
- Trans-rectal	√	√	√	√	√	√
- Trans-vaginal	√	√	√	√	√	√
- Musculo-skeletal (Conventional)	√	√	√	√	√	√
- Musculo-skeletal (Superficial)	√	√	√	√	√	√
- Urology	√	√	√	√	√	
- Cardiac Adult	√		√	√	√	√
- Cardiac Pediatric	√		√	√	√	√
- Peripheral vessel	√	√	√	√	√	√
Scanhead Types						
- Linear Array	√	√	√	√	√	√
- Curved Linear Array	√	√	√	√	√	√
- Endocavity	√	√	√	√	√	√
- Phased Array	√		√	√	√	√
- Static Probes			√	√	√	√
Scanhead Frequency						
1.0 ~ 20.0 MHz	√	√	√	√	√	√
Modes of Operation						
- B-mode	√	√	√	√	√	√
- M-mode	√	√	√	√	√	√
- Pulsed wave (PW) Doppler	√	√	√	√	√	√
- Continuous wave (CW) Doppler	√		√	√	√	√
- Color Doppler	√	√	√	√	√	√
- Power Amplitude Doppler	√	√	√	√	√	√
- Tissue Harmonic Imaging	√	√	√	√	√	√
- 3D/4D imaging mode	√	√	√	√	√	√
- Combined modes	√	√	√	√	√	√
Safety & EMC Compliance						
- IEC 60601-1						
- UL 60601-1	√	√	√	√	√	√
- CSA C22.2 No.601.1						

Feature / Characteristics	The subject device	The predicate devices				
	WS80A	UGEO WS80A (K133329)	RS80A (K141620)	UGEO H60 (K132861)	Voluson E8 (K122327)	ACUSON S2000 (K130739)
- IEC 60601-2-37	√	√	√	√	√	√
- IEC 60601-1-2	√	√	√	√	√	√
Acoustic Output Display Standard						
Track 3	√	√	√	√	√	√
Patient Contact Materials						
Tested to ISO 10993-1	√	√	√	√	√	√
Functionality						
- Quick Scan (Q Scan)	√	√	√	√		
- Spatial Compound Imaging	√ ¹⁾	√	√	√		
- SMDR (SMDR evo)	√ ²⁾	√	√	√		
- Auto IMT+ (Auto IMT)	√	√	√	√		
- Elastoscan	√	√	√			
- Panoramic	√	√	√			
- 3D Imaging (Volume Data Acquisition)	√	√	√	√		
- 3D Imaging presentation 3D Cine/4D Cine 5D Cine	√ √	√ √	√	√		
- 3D Rendering MPR(Multi Planer Render)	√	√	√	√		
- 3D XI MSV(Multi Slice View) Oblique View	√	√	√	√		
- 3D MXI Volume Slice, Mirror View	√	√	√			
- XI Volume CT (Volume CT)	√	√	√			
- 3D MagiCut	√	√	√	√		
- Volume Calculation (VOCAL, XI VOCAL)	√	√	√	√		
- XI STIC	√	√	√			
- HDVI	√	√	√			
- FRV	√ ³⁾	√				
- Volume NT/IT	√	√	√	√		
- 5D NT	√	√				
- 2D NT	√	√				
- ADVR	√	√	√			

Feature / Characteristics	The subject device	The predicate devices				
	WS80A	UGEO WS80A (K133329)	RS80A (K141620)	UGEO H60 (K132861)	Voluson E8 (K122327)	ACUSON S2000 (K130739)
- 5D LB	√	√				
- MPI	√	√				
- 5D CNS	√					√ ⁽⁴⁾
- 5D Follicle	√				√ ⁽⁵⁾	
- 5D Heart	√				√ ⁽⁶⁾	

1) The name of the feature is changed to MultiVison.

2) The name of the feature is changed to ClearVision

3) The name of the feature is changed to Realistic Vue.

7. A brief discussion of the bench and non-clinical tests conducted on the subject device

The device has been evaluated for acoustic output, biocompatibility effectiveness as well as thermal, electrical, electromagnetic and mechanical safety and has been found to conform to applicable medical device safety standards.

The WS80A and its application comply with voluntary standards as below:

- UL 60601-1, Safety requirements for Medical Equipment
- CSA C22.2 No. 601.1, Safety requirements for Medical Equipment
- IEC60601-2-37, Diagnostic Ultrasound Safety Standards
- EN/IEC60601-1, Safety requirements for Medical Equipment
- EN/IEC60601-1-2, EMC requirements for Medical Equipment
- NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- ISO10993-1, Biocompatibility
- ISO14971, Application of risk management to medical devices

Summary of Clinical Tests:

Not applicable. The subject of this submission, WS80A, did not require clinical studies to support substantial equivalence.

8. Conclusion

Intended uses and other key features are consistent with traditional clinical practices and FDA guidelines. The design, development and quality process of the manufacturer confirms with 21 CFR 820 and ISO 13485. The device is designed to conform to applicable medical device safety standards and compliance. Therefore, SAMSUNG MEDISON CO., LTD. considers the WS80A to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

END of 510(K) Summary